COVID-19 Therapeutics Information Brief

June 29, 2022

Changes to the document from the previous version are highlighted in yellow.

The next Therapeutics Information Brief will be July 13, 2022.

IMPORTANT/NEW COVID-19 Therapeutics Information

- July 4th Holiday Ordering Cadence
- Evusheld Shelf-Life Extension Authorized - NEW
- REGEN-COV Shelf Life Extension
- Therapeutic Reporting Cadence - Browser Update
- Allocations Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals
- COVID-19 Therapeutics Information Resources

July 4th Holiday Ordering Cadence

The ordering cadence for the week of July 4, 2022 will be as follows:

- Allocation Survey Sent - **Tuesday, July 5, 2022**
- Allocation Survey Due Back to IDPH - **Wednesday, July 6, 2022 at 4:00 pm**
- Allocation Ordered in Federal System - Thursday, July 7, 2022
- Allocation Amount Notification from IDPH to healthcare providers - Thursday, July 7, 2022

Evusheld Shelf-Life Extension Authorized - NEW

On June 28, 2022, the Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) announced the authorization of an extension to the shelf-life from 18 months to 24 months for specific lots of the refrigerated AstraZeneca monoclonal antibody therapy, Evusheld (tixagevimab co-packaged with cilgavimab), which is currently authorized for emergency use for pre-exposure prophylaxis of COVID-19 in certain adults and pediatric individuals.

As a result of this extension, some batches may be stored for an additional 6 months from the labeled date of expiry (see Table 1 below) and, as required by the emergency use authorization for Evusheld, unopened vials of Evusheld (150 mg/1.5 mL of tixagevimab and 150 mg/1.5 mL of cilgavimab), must be stored under refrigerated temperature at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. FDA granted this extension following a thorough review of data submitted by AstraZeneca. This extension applies to all unopened vials of Evusheld that have been held in accordance with storage

conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization for Emergency Use Authorization (EUA) 104 for Evusheld.

Evusheld has fixed expiration dates on the label of each vial and carton. The date identified on the vial and carton reflects the original shelf-life of 18 months and does not reflect the extended 24-month shelf-life. The table below provides a list of the updated expiry, by batch, for distributed Evusheld. If the batch number on the vial/carton is not included in this listing, the product is labeled with the correct expiration date.

Table 1: Extended Expiry Dating for Evusheld (Tixagevimab Co-Packaged with Cilgavimab) Authorized under EUA 104

Co-Pack Lot Numbers	Labelled Co-Pack Expiration Dates	Extended Co- Pack Expiration Dates	Component Lot Numbers
AZ210059	Jul 2022	Jan 31, 2023	Cilgavimab: 2100505 Tixagevimab: 2100511
AZ210062	Jul 2022	Jan 31, 2023	Cilgavimab: 2100505 Tixagevimab: 2100511
AZ210065	Jun 2022	Dec 31, 2022	Cilgavimab: 2100503 Tixagevimab: 2100509
AZ220033	Aug 2022	Feb 28, 2023	Cilgavimab: 2100550 Tixagevimab: 2100551
AZ220036	Aug 2022	Feb 28, 2023	Cilgavimab: 2100552 Tixagevimab: 2100549
AZ220061	Aug 2022	Feb 28, 2023	Cilgavimab: 2100552 Tixagevimab: 2100549
AZ220042	Jul 2022	Jan 31, 2023	Cilgavimab: 2100552 Tixagevimab: 2100511
AZ220053	Jul 2022	Jan 31, 2023	Cilgavimab: 2100507 Tixagevimab: 2100509
AZ220059	Jul 2022	Jan 31, 2023	Cilgavimab: 2100507 Tixagevimab: 2100511
AZ220056	Jul 2022	Jan 31, 2023	Cilgavimab: 2100507 Tixagevimab: 2100513

REGEN-COV Shelf Life Extension

The FDA authorized an extension to the shelf-life from 24 months to 30 months for specific lots of the refrigerated Regeneron monoclonal antibodies, casirivimab and imdevimab, administered together or REGEN-COV. Extended expiry dates can be found here.

Due to the high frequency of the Omicron variant and its subvariants, REGEN-COV is not currently authorized in any U.S. region. Therefore, REGEN-COV may not be administered for treatment or post-exposure prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency. However, it is the recommendation of the U.S. Government that the product be retained in the event that future SARS-CoV-2 variants, which may be susceptible to REGEN-COV, emerge and become prevalent in the United States.

Retained product must be appropriately held in accordance with storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization for Emergency Use Authorization (EUA) 091. These recommendations apply to all unopened vials of casirivimab, imdevimab, and REGEN-COV that have been held in accordance with storage conditions (refrigerated temperature at 2°C to 8°C [36°F to 46°F]) detailed in the authorized Fact Sheet for Health Care Providers for EUA 091 for casirivimab and imdevimab, administered together.

Therapeutic Reporting Cadence

Sites receiving monoclonal antibodies, pre-exposure prophylaxis treatment, or oral antivirals MUST comply with federal reporting requirements.

Failure to comply with reporting requirements may result in the loss of COVID-19 therapeutic providers status and removal of COVID-19 therapeutic products. **Reporting requirements are as follows:**

- Monoclonal antibodies (REGEN-COV, bamlanivimab/etesevimab, sotrovimab): Report on-hand and usage data **every Wednesday** in NHSN (for long-term care facilities) or Teletracking (for all other sites including hospitals).
- Pre-exposure prophylaxis treatment and oral antivirals (Evusheld, Paxlovid, Molnupiravir and Bebtelovimab): Report on-hand and usage data **twice per week** in HPoP.
    - **Reporting should be completed by 11:59 pm on MONDAY and THURSDAY**
    - **Internet Explorer is NOT supported, please use Chrome, Firefox, Edge or Safari**
- Reporting should include product doses utilized since the last report date
- Reporting **IS NOT** a cumulative total of all doses utilized to date
- Please contact C19therapeutics@idph.iowa.gov for assistance with HPoP

Healthcare providers should ensure reporting of the correct Paxlovid or Renal Paxlovid product. Paxlovid (renal) was renamed as Renal Paxlovid and the display order was changed to separate the Paxlovid products.

Allocations Threshold Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals

Iowa Statewide Allocations Threshold Remaining for the week Monday, June 27, 2022 - Sunday July 3, 2022				
mAbs	Oral AVs			PrEP
Bebtelovimab	Mulnupiravir (Lagevrio)	Paxlovid	Renal Paxlovid	EVUSHELD
165 courses	**312 courses**	**880 courses**	**80 courses**	**1824 doses** (monthly allocation)

- The minimum order quantity for Molupiravir is 24 courses.
- **Allocations will not include sotrovimab, bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV).**
- **IDPH encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.**
- The Department of Health and Human Services has released a COVID-19 Therapeutics locator.

COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center -** To reach the IDPH COVID-19 Therapeutics Call Center, call **515-281-7317**.
- **COVID-19 Therapeutics Email -** Therapeutic questions from healthcare providers can be emailed to: C19Therapeutics@idph.iowa.gov
- **COVID-19 Therapeutics Table-** IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.
- Outpatient Therapeutics Decision Aid
- Side-by-Side Overview Outpatient Therapeutics
- NIH COVID-19 Treatment Guidelines